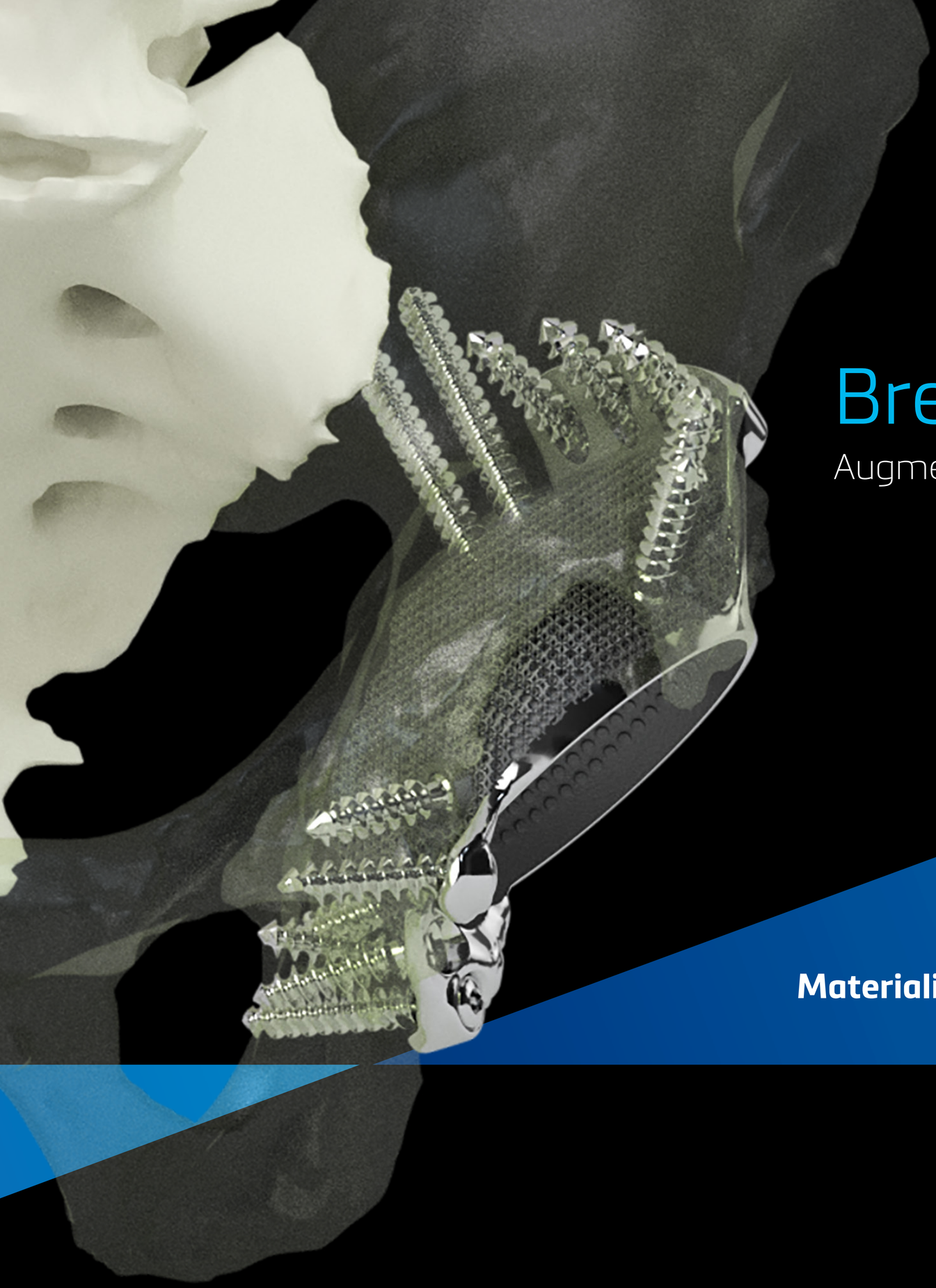


Break the revision cycle

Augment the predictability, trust the outcome

Materialise aMace Patient-Specific Acetabular Implants

materialise

innovators you can count on

Make Mobility Sustainable with Materialise aMace

Up to 27% of hip revisions are re-revisions due to a suboptimal fixation and suboptimal biomechanical reconstruction of the joint[1] when combining standard components. What's even worse,
hip re-revisions are 3 times more likely to fail compared to a primary acetabular revision[2]. As the spiral of revisions heads downwards, your patients experience more pain, anxiety and risk. Some have difficulties walking or they rely on a wheelchair. As defects become more severe, surgeries become more challenging.

Time to end the necessity for future revisions. Augment the predictability of your surgery with the Materialise aMace acetabular implant, and boost the chances of a positive outcome for your patient. A 98% implant survival (1/58 at mean follow-up time of 25 months, Baauw et al., 2017[3], 2015[4]; Citak et al., 2017[5]; Colen et al., 2013[6]; Myncke et al., 2017[7]), and 100% of patients feeling satisfied with the results (18/18, Baauw et al., 2017[3]; Colen et al., 2013[6]), what's not to like?

Materialise aMace is a titanium acetabular implant designed to break the revision cycle. Each acetabular implant is patient-specific and is based on a thorough presurgical 3D analysis. Design is done in collaboration with a clinical engineer, focused on optimizing implant fixation and minimizing dislocation risk to further support long-term results. The aMace is a convenient one-piece solution with integrated flanges, augment, and cup, which removes the need to intraoperatively select and combine standard components, and ultimately, eliminates the risks of intercomponent movements.

Indications:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Posttraumatic and rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments or devices have failed
- Treatment in conjunction with tumor resection

"This solution offers the possibility to regain full quality of life for patients with complex acetabular defects, lower the risk of re-revisions, immobility and permanent care."

Prof. Dr. Med. T. Gehrke, chief physician,
HELIOS ENDO-Klinik Hamburg, Germany

Advanced 3D planning gives you the added confidence of knowing what to expect during your surgery, so that fewer surprises pop up in the OR.

The philosophy behind our solution is to **adapt the implant to the patient** instead of the other way around. This translates into preserving bone stock, avoiding reaming, and making the implant fit and adapt to healthy anatomy, instead of removing bone to fit the implant. It's all about the patient.

A 98% implant survival, and 100% of patients feeling satisfied with the results, what's not to like?

Why is Materialise aMace so amazing?

Feel confident about 3D Planning

Surgeons report a high satisfaction rate (8/10 Mycke et al.;2017[7]) after having worked with our renowned and highly professional clinical engineers.

During the analysis and design, our clinical engineers rely on the **most advanced software to visualize the available bone stock, and on A.I. technology based on population data to quantify acetabular bone loss**. These unique capabilities are both critical for an optimal reconstruction and fixation. The personalized solution allows the planning of the center of rotation and inclination, and anteversion angles. Close collaboration between engineers and surgeons results in a preoperational report, including the meticulous planning of screw length, position and direction, and the design of the patient-specific trabecular augment.

With preoperative planning, a detailed screw plan, plus 3D Printed models, you and your surgical team can offer the patient a clearer understanding of the procedure, and **enter the OR optimally prepared, knowing there will be less intraoperative decisions to take.** The accurate 3D bone model of the patient's anatomy is a tangible reference during surgery.

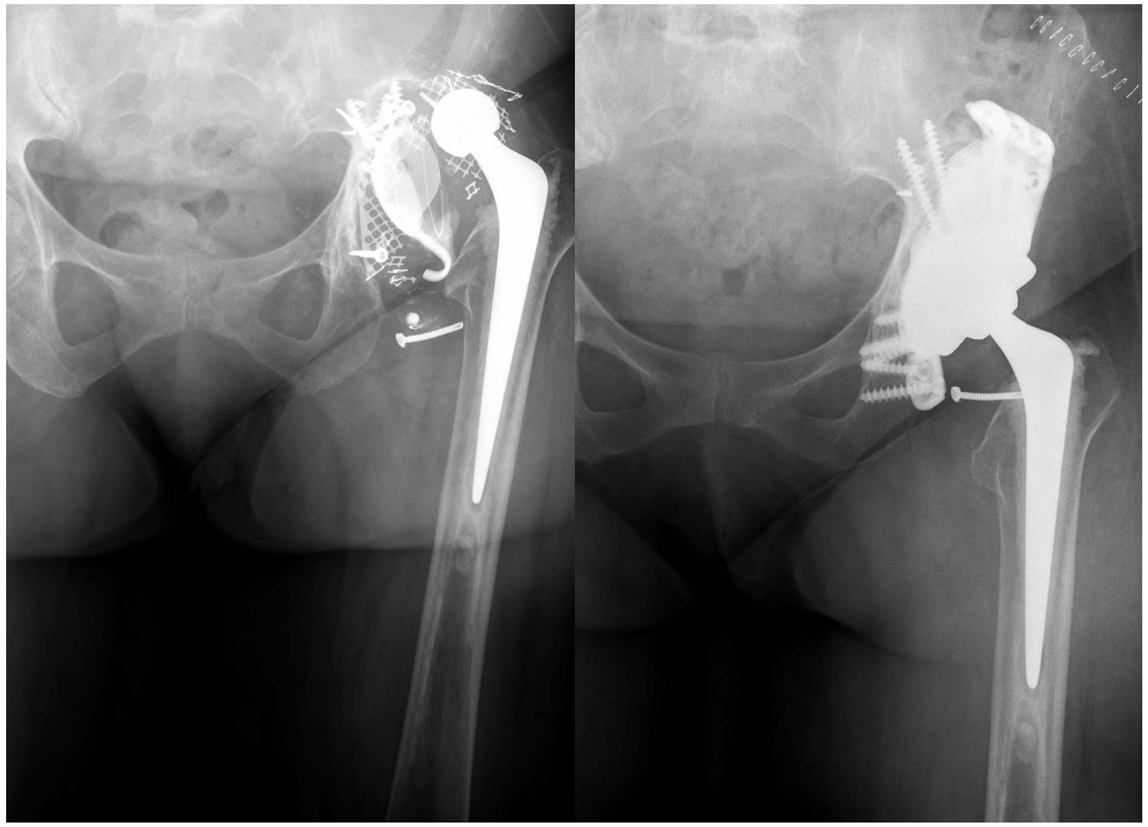
“To me, reducing your surgical time is an important advantage of these custom-made implants. I’m very well prepared before I go into an operation.”

Prof. Dr. Med. G. Flivik, associate professor
Department of Orthopedics Lund University, Sweden

Trust a 98% implant survival

That’s right. Our success is founded on 10 years of experience in treating arthroplasty cases, 27 years of experience in the 3D software business, and on having created more than 350,000 patient-specific guides and implants. 50,000 patients from around the globe benefit from our solutions year after year.

Our tailored hip implant boasts a high implant-associated survival rate of 98%. The high success rate is attributed to an **implant that is stable and biomechanically optimized**. The personalization creates optimal primary and secondary fixation, prolong stability, and decrease the risks of dislocation. The aMace is a comprehensive solution beneficial to both patient and surgeon.



“There are a number of patients who were confined to a wheelchair before the operation, and who were able to live independently again after we had placed the implant.”

Dr. van Hellemondt, orthopedic surgeon
Sint-Maartenskliniek, Nijmegen, the Netherlands

Optimize the long-term fixation and stability

The extensive 3D analysis has for purpose to mitigate the risk of dislocation and to optimize the stability of the implant by **planning the position of the center of rotation, cup inclination and anteversion preoperatively.**

We reduce the risk of loosening by providing a **one-piece patient-specific design with an integrated trabecular augment and patient-specific screw fixation**. Studies focusing on nearly 70 cases report no signs of radiological loosening up to 2 years post-surgery (0/69 [3,4,5,6,7,8]).

Moreover, the patient-specific trabecular structure extends to the flanges and augment, and **allows bone ongrowth, thanks to its porous structure.** The compact and light implant has been designed to minimize soft tissue damage or irritation.

Materialise aMace Patient-Specific Acetabular Implants

Rely on a very high patient and surgeon satisfaction rate

The aMace solution yields a high satisfaction rate amongst patients. Post-operative studies indicate that **almost every patient (98%) would repeat the procedure** (Baauw et al., 2017)[3]**.** The overall majority (92%) would recommend the surgery to a family member or friend (Baauw et al., 2017)[3].

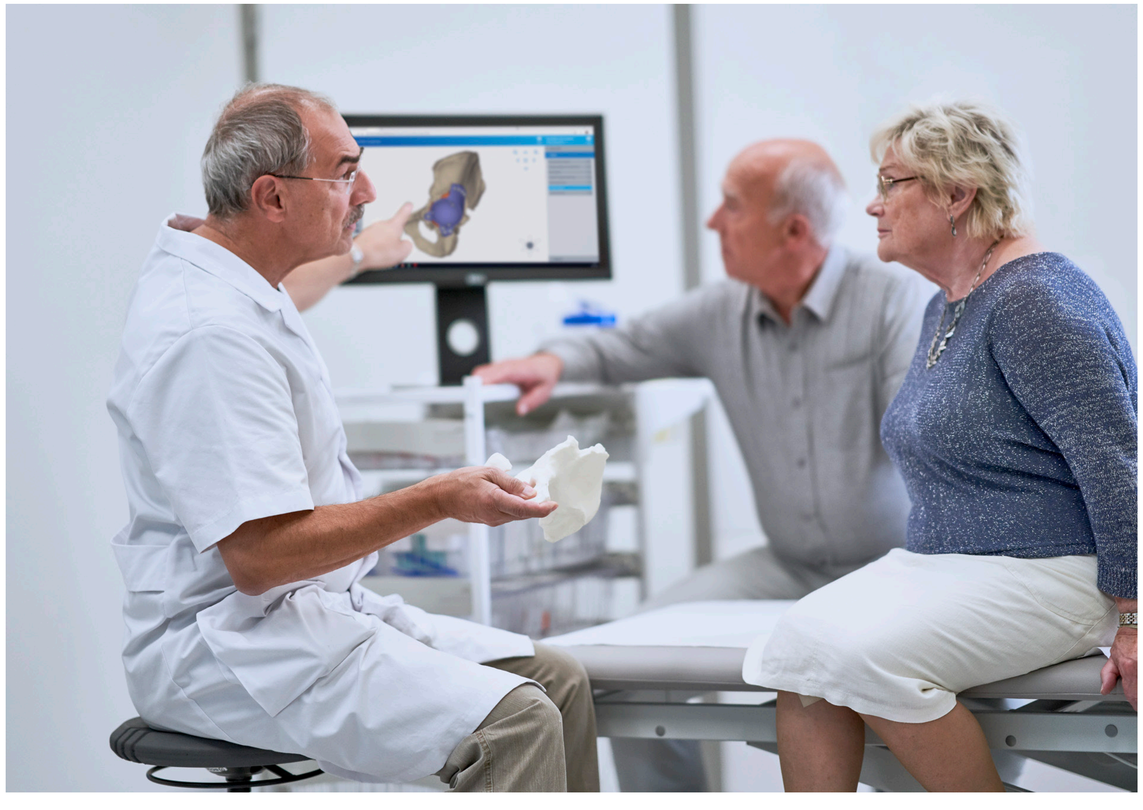
According to various references, the overall majority of patients (83%) report **less pain and more mobility** after having received a Materialise aMace implant (Baauw et al., 2017)[3]. In one specific study, the Harris Hip Score went up from 22/100 pre-surgery to an average of 59/100, 2.5 years following surgery (Citak et al., 2017)[5].

Surgeons tell us they are **highly satisfied after having worked with our clinical engineers** when customizing the Materialise aMace solution for their patients (81%, Myncke et al., 2017[7]). They also report that the implant contributed additional ease to complex procedures (73%, Myncke et al., 2017[7]).

The personalized hip implant creates a positive impact on your patients' daily lives, and on your procedures. So, why not opt for an implant that will benefit everyone?

"Interfacing with the engineers is straightforward and first rate, leaving you with a sense of confidence, which is an important part of a surgeon's preoperative approach to these challenging cases."

Prof. D. Dunlop, consultant orthopedic surgeonn
Southampton University Hospital, Southampton, UK



Discover the Unique Features of Materialise aMace

Unique 3D Analysis of the acetabulum using Artificial Intelligence

The aMace solution starts with our core strength: a detailed preoperative planning that includes a unique patient-specific analysis of the hip. For this analysis, our clinical engineers use our in-house developed pre-operative planning software, Materialise Mimics, which has been leading the industry for over 27 years.

Based on segmented 3D scans, we reveal an **extensive 3D visualization** of the acetabulum including all components of the pelvis such as previous implant, screws, cement, and more.

Our clinical engineers measure **thickness of the bone** and individual cortex to visualize available bone stock, both critical for an optimal implant fixation.

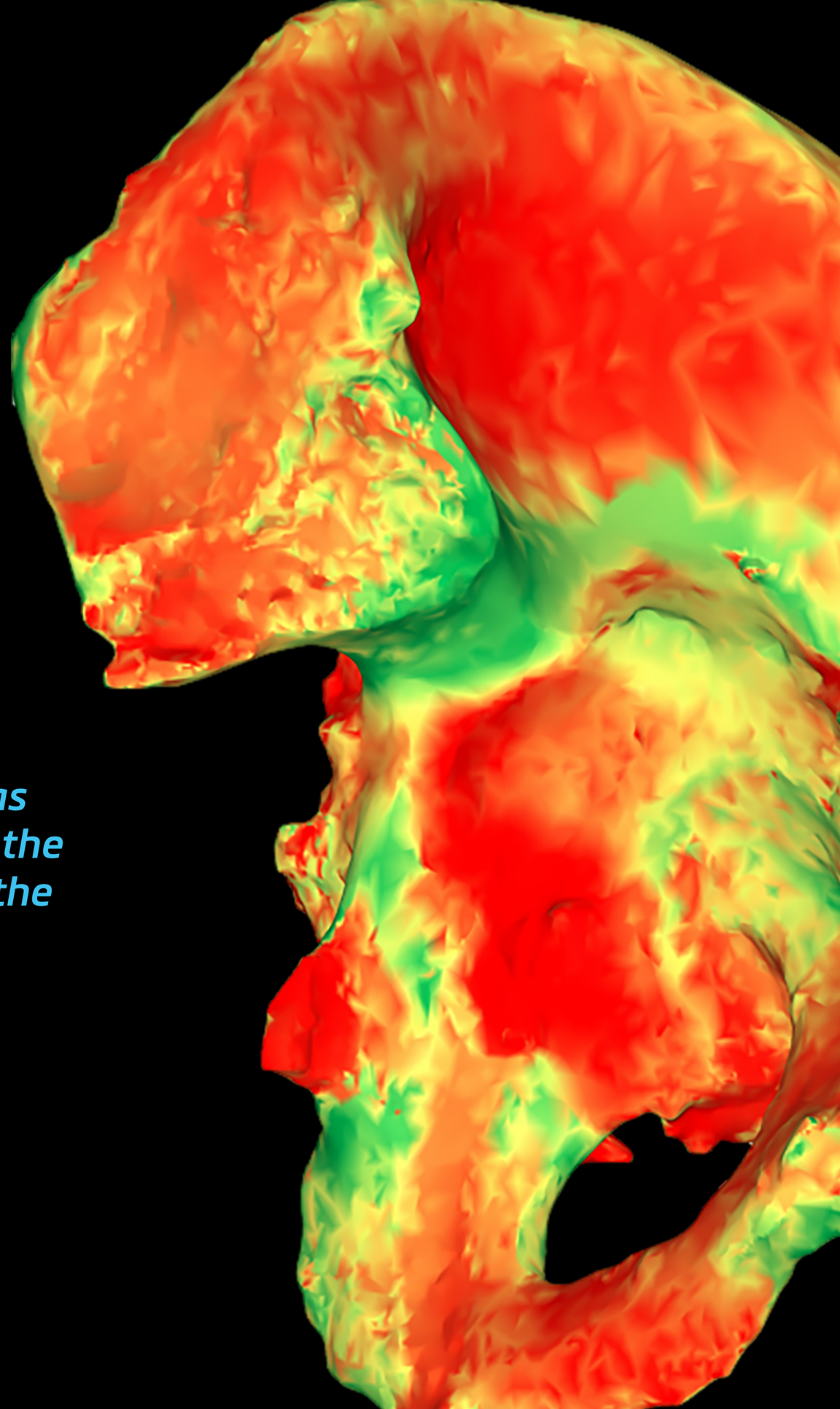
Our team uses a patient-specific color map to quantify the acetabular bone loss and compare the patient's defect to the **simulated healthy acetabulum**, using A.I. technology based on population data.

“It’s like having a manual: I know what to do, I know the bone quality, I know the good and the bad parts of the pelvis.”

Prof. Dr. Med. G. Flivik, associate professor
Department of Orthopedics Lund University, Sweden

“I was confident that the aMace implant was the right choice for my patient because of the attention for the biomechanical aspect in the design of the implant.”

Dr. Henrik Delport, orthopaedic surgeon and consultant
AZ Nikolaas, Belgium



“The drill guides give me confidence about the positioning of the screws, which helps save time.”

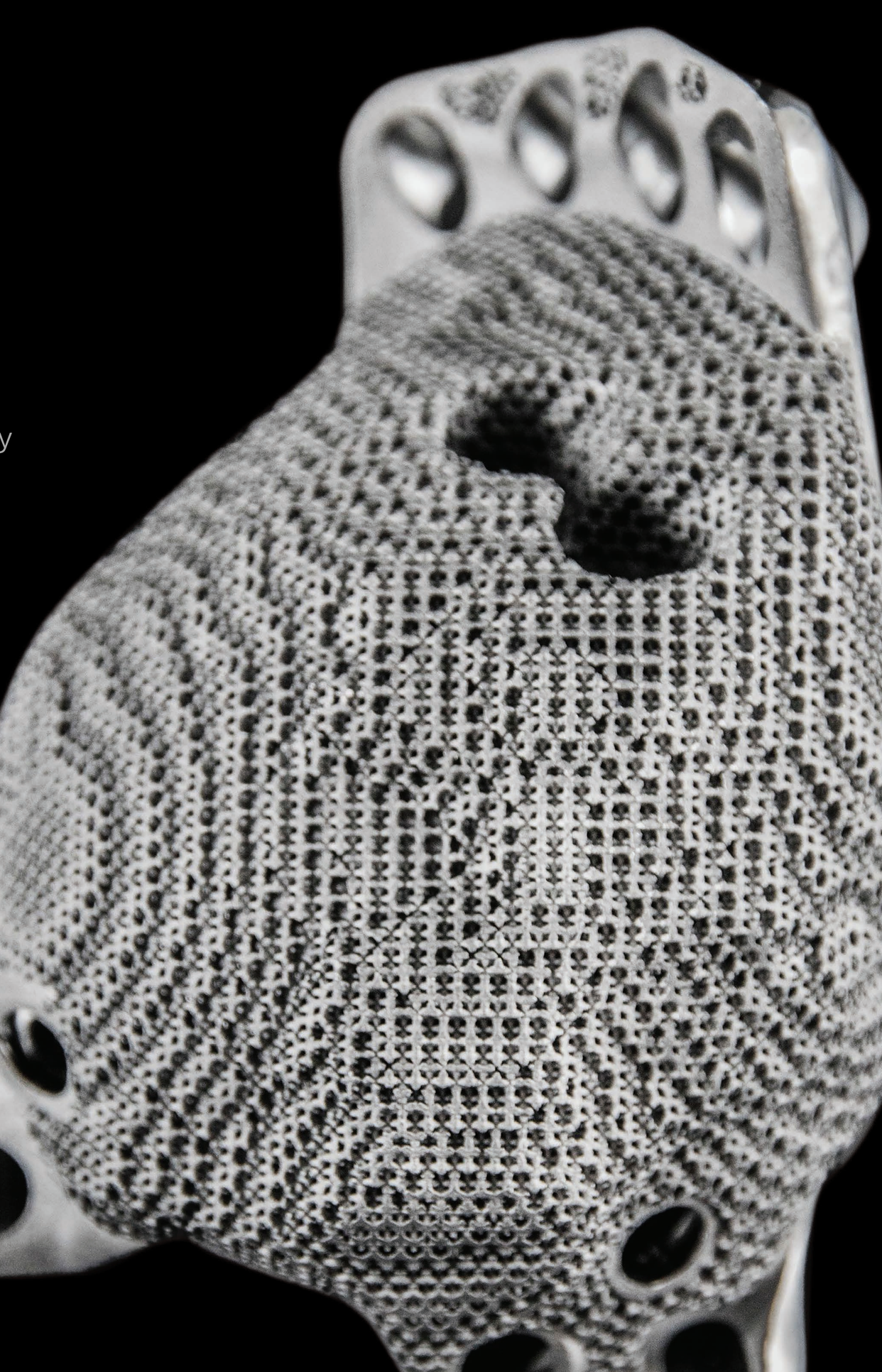
Prof. Dr. Med. G. Flivik, associate professor
Department of Orthopedics Lund University, Sweden

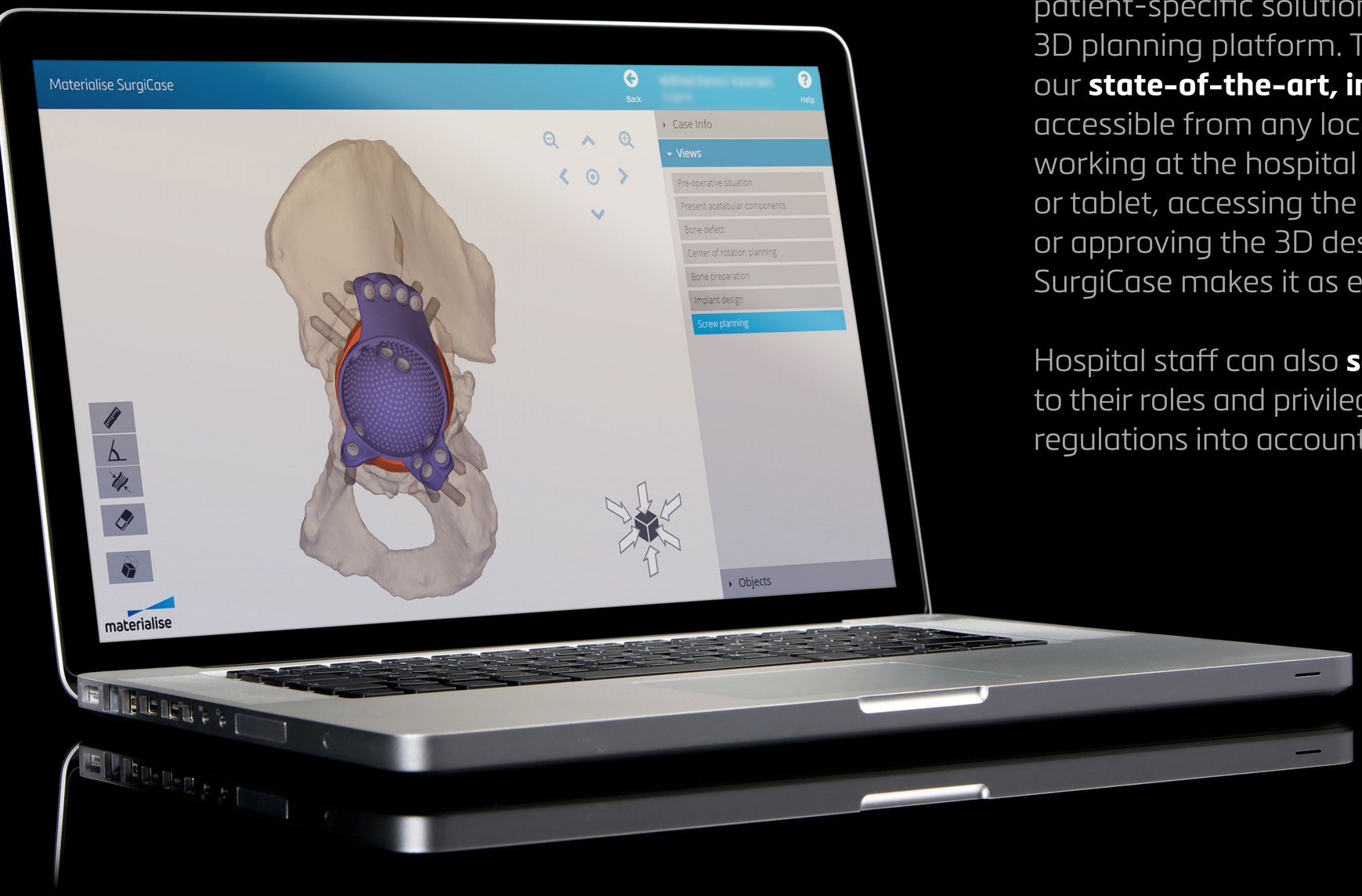
Patented drill guides

We’ve gained our extensive experience by designing and printing over 200,000 patient-specific knee, hip and shoulder guides, and have enhanced our solution by adding unique drill guides that match the patient-specific implant. This will **solidify surgeons’ confidence** further for even the most complex acetabular procedures. The patented guides[9] are designed to make surgery even more predictable by supporting the meticulous positioning of cross-fixated screws during surgery and thus **securing an optimal primary fixation.**

Trabecular biocompatible augment

The implant and augment are made of highly biocompatible titanium alloy, Ti6Al4VELI. The material's porous structure, an interconnected network of pores providing an average porosity of 70%, is designed to **mimic properties of trabecular bone**, to allow bone ongrowth. The trabecular augment not only makes the implant light, but also **improves secondary fixation, and maximizes bone preservation**.





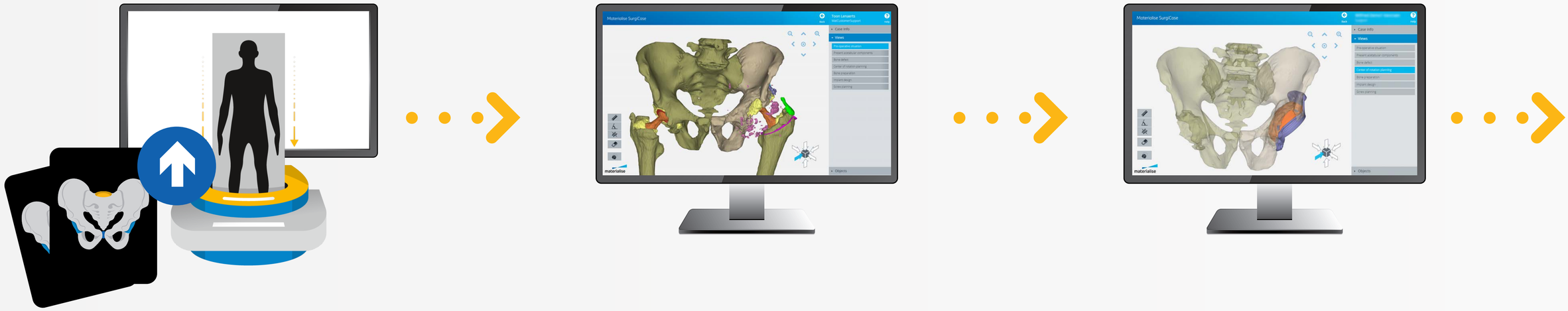
Easy-to-use digital collaborative platform

Work together with your team and our engineers on your patient-specific solution with Materialise SurgiCase, our online 3D planning platform. This online platform incorporates our **state-of-the-art, in-house developed software**, and is accessible from any location on any device. Whether you're working at the hospital or from home using your computer or tablet, accessing the preoperative plan, giving feedback or approving the 3D design, checking the status of the order, SurgiCase makes it as easy as it gets.

Hospital staff can also **securely work on the platform**, according to their roles and privileges. The online platform takes all privacy regulations into account and is fully GDPR ready.

Materialise aMace Patient-Specific Acetabular Implants

Ordering Process



Uploading CT scans

Your account manager will create an account on our SurgiCase platform for you and your hospital administration. Once you're logged in, you can upload your CT scans onto the planning platform. Make sure that the scans you use are compliant with the requirements of the Materialise Scan Protocol.

3D analysis

After visualizing the patient's bone defects and present components in 3D, our clinical engineers map out the acetabular defect in terms of missing bone and thickness. Next, we perform an acetabular bone loss analysis to compare the patient's condition with a healthy acetabulum.

Design of the implant

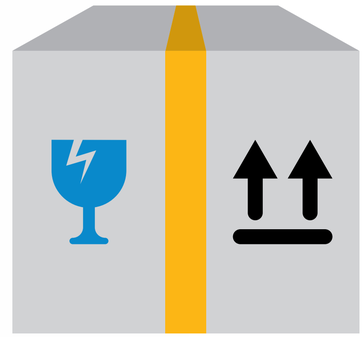
The design of the implant is based on the ideal center of rotation (COR) and bone preservation. Our clinical engineers determine the relevant measurements and ideal screws positioning. Using the collaborative SurgiCase platform, you can review the design proposal and give us your feedback directly in SurgiCase.

1 week

You can expect to review the implant design **as soon as one week after you've uploaded the digital images.**

Production of the patient-specific parts

Once the design of the implant has been approved, the 3D printing process of the patient-specific device begins at our certified medical 3D printing facilities. As part of the Materialise aMace package, patented drill guides, an implant trial model and an accurate bone model of the patient's defect, will be included.



Get the package

It's time to receive the package at your hospital. This includes the case report with all the data pertaining to the case, the surgical technique, surgical poster and sterilization instructions.

± 4 weeks

Do you have questions?
We're here to answer.

"The aMace implant was preferred over other solutions because it offers a complete solution, much more patient-specific than any other implant, through calculations – scientifically validated by peer-reviewed research – of the optimal implant thickness and strength, best position of screws according to bone quality and analysis of the impact on biomechanical functioning of a specific patient."

Prof. Dr. Med. T. Gehrke, chief physician, HELIOS ENDO-Klinik Hamburg, Germany

For which patient is this technology suitable?

We see that most cases are Paprosky IIIA and IIIB types, however, the advantageous Materialise acetabular system has been used in type II, dysplastic and tumor cases as well. It is intended for revision surgeries as well as primary surgeries. And naturally, as the implant is 3D printed, thus custom-made for each patient, it is not limited to severe cases. It can fit any defect.
The medical indications can be summarized as follows:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Posttraumatic and rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments or devices have failed
- Treatment in conjunction with tumor resection where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum

Why choose a custom solution over a standard implant?

Although a standard solution may be the best one for a standard case, a patient-specific implant is often better suited for more challenging defects. With a Materialise aMace solution, you receive an implant which is pre-operatively designed to match the patient, and optimized for stability and biomechanical performance, resulting in a 98% implant survival. With the implant, you receive patient-specific drill guides, an extensive unique 3D analysis of the acetabular defect and planning for your surgery. Compared to standard implants, whose multiple components need to be pieced intra-operatively, under stress and time pressure, thus jeopardizing

the performance, our one-piece solution eliminates the entire process of selection and assembly, and the risks of intercomponent movements altogether.

In addition, Materialise aMace comes with an exclusive team of clinical engineers, always there for you to discuss the implant design and surgical planning. This gives you the assurance and confidence that the operation will be without surprises.

Contrary to standard implants where the cost can increase over time depending on the clinical outcome, the cost is calculated upfront. The transparency and high-tech value of the experience makes it a trustworthy technical and reliable solution.

After having compared alternative solutions on the market, we've seen that preliminary data10 suggests that the aMace is a more cost-effective solution to treat complex acetabular defects.

Is there evidence on patient-specific implants? Can I trust it?

Materialise has 10 years of experience in treating arthroplasty cases, 27 years of experience in the 3D software business and has already created more than 350,000 patient-specific guides and implants. More than 700 patients worldwide were helped with this patient-specific hip implant so far. We currently have published evidence on 10% of our total experience.

The results are very reassuring: the published follow-up data (mean follow-up of 2 years, which is the typical timeframe for early failures) result in 98% implant survival[3] rate and 100% improved patient outcome[4].

Download the full clinical data summary.

What's the reimbursement process?

Reimbursement processes differ per country. They are dependent on legislation or on hospitals' contracts with insurance companies, DRG systems or special funds.

If you would like to know the specific reimbursement possibilities applicable to your country even before the planning phase, contact us and we will inform you right away.

In which country is the product available?

Currently, Materialise aMace is sold directly in Australia and Europe (Austria, Belgium, Finland, France, Germany, Ireland, the Netherlands, Norway, Sweden and United Kingdom). In Poland, our solutions is sold through a distributor. It is not yet commercially available in Canada and the US.

Collaborate with Materialise to break the revision cycle

You can break this downward spiral. Don't compromise. With a **98% implant survival**, you can promise your patients a better outcome.

Rely on the proven advantages of the Materialise aMace solution:

- Added confidence and ease-of-use
- Optimal preparation for surgery
- Proven high patient and surgeon satisfaction

"Before, the outcome was a lottery, no guarantees. Now we can reassure our patients. We haven't had to break our word yet.

Prof. Dr. Van Overschelde, Orthopedic surgeon, hip and knee, AZ Middelares, Belgium

[1] Swedish Arthroplasty Register, Annual Report 2014
[2] Data UK Joint Registry
[3] Baauw M, van Hellemondt GG, Spruit M. A custom-made acetabular implant for Paprosky type 3 defects. Orthopedics 2017;40(1):195-198.
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[7] Myncke I, van Schaik D, Scheerlinck T. Custom-made triflanged acetabular components in the treatment of major acetabular defects. Short-term results and clinical experience. Acta Orthop Belg 2017;83:341-350.
[8] J. Demol, B. Lenaerts, S. Leuridan, S. De Boodt, P. Delport. Bone ingrowth and biological fixation of selective laser melted porous scaffolds for the reconstruction of severe bone defects. Journal of Tissue Engineering and Regenerative Medicine 2012, 6 (Suppl 1), 401
[9] AU2010338263, AU2013270531, AU2015261671, DE60 2010 022 243.8, EP2519165(BE, CH, DK, FR, FI, GB, IE, LU, NL, SE), JP6196446B, US9,498,234,US9,808,261
[10] Tack P. 3D is Here, But Can We Afford It Moving Forward? Materialise World Summit, 20-21 April 2017, Brussels, Belgium. Materialise Blog post (publication in progress)

Contact your local sales representative today or take a look at the website **materialise.com/aMace**, we can offer you:

- Clinical Data Summary
- Demo Case Report
- Webinars
- Surgical videos
- Case stories
- Blog posts
- Tutorials

New to Materialise? Receive a free 3D analysis of your next case.

Do you have a hip re-revision case in mind or are you treating a patient with significant acetabular bone deficiencies? Then we can work on a 3D Planning report to give you an idea of the solutions we can offer.

Go to this webpage, fill out the contact form and we'll get in touch. We'll setup a user account on our SurgiCase platform and send you instructions on how to upload your CT images. Afterwards, we will contact you to discuss the case report.

About Materialise

27 years of experience have inspired and empowered us to create a range of software solutions and 3D printing services that have become the backbone for the 3D planning and printing industry.

Materialise fully acquired the company Mobelife (which introduced the aMace Acetabular Revision System) in 2015. Now, with more than 10 years' experience in orthopedics ranging from knee, shoulder, hip and osteotomy guides, to patient-specific hip and shoulder implants, our highly qualified group of clinical engineers is working with the biggest implant manufacturers in the world.

With our people and technology, we want to co-create a better and healthier world. And this starts by always being there for you.

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L-11024-01

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